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Message to Supervisory Examiner Page

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Comments:

Application Serial Number: 09/816,284
Inventor: Stephen Paul Bartels et al.

Attached find a summary of that portion of the April 28, 2003 interview relating to zinc and copper as requested.

09/816,284

Summary of Copper and Zinc Discussion of April 28, 2003

Copper is important for normal hemoglobin production. High levels of zinc consumption can interfere with copper absorption and can induce anemia. As set forth in AREDS Report No. 8 titled *"A Randomized, Placebo-Controlled, Clinical Trial of High-Dose Supplementation With Vitamins C and E, Beta Carotene, and Zinc for Age-Related Macular Degeneration and Vision Loss"* (hereinafter "AREDS Report") on page 1418, the supplements (composition of the present invention) contained 2 mg copper as cupric oxide to prevent potential anemia. It was also noted in the AREDS Report on page 1419, that the study participants [Category 1 subjects] were at low risk for vision loss from AMD and there was no reason to suspect that zinc use would reduce the risk of progression of lens opacities. Because there was no apparent reason for these participants to supplement their diets with zinc, it seemed inappropriate to subject them to the possible consequences of high levels of zinc supplementation, i.e., induced anemia. At the time of enrollment, participants were informed of possible adverse effects of and contraindications to the use of study medications including zinc because of risk of anemia (AREDS Report, page 1420). Hematocrit was measured at all centers on all participants at baseline and annually thereafter to monitor the possible development of anemia (AREDS Report, page 1420). A subset of participants was monitored for lipid and copper levels and the entire cohort was monitored for hematocrit because of potential concerns about the high doses of zinc given. No statistically significant effect of zinc supplements on hematocrit or serum levels of lipid or copper was observed (AREDS Report, page 1432). Accordingly, the level of copper provided in the subject composition was sufficient and critical to prevent zinc-induced anemia.

The relationship of copper in the subject composition to minimize or eliminate zinc-induced anemia is described in the specification of the subject application on pages 17 and 18, paragraphs [0033] and [0034].

Applicants also presented arguments noting the AREDS Report results illustrating the surprising beneficial effects of the present invention over the use of antioxidants – vitamins A, C and E alone (ineffective) or zinc and copper alone (ineffective). The only statistically significant reduction in the rates of at least moderate visual acuity loss occurred in persons assigned to receive antioxidants plus zinc (AREDS Report, page 1417).

Should there be any questions regarding this communication, please feel free to contact the undersigned at (636) 226-3340.

Respectfully submitted,

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